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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference PCT1218-066	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP00/08808	International filing date (day/month/year) 08 September 2000 (08.09.00)	Priority date (day/month/year) 24 September 1999 (24.09.99)
International Patent Classification (IPC) or national classification and IPC C12Q 1/68		
Applicant BIOTECON DIAGNOSTICS GMBH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 16 March 2001 (16.03.01)	Date of completion of this report 30 January 2002 (30.01.2002)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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I. Basis of the report

1. With regard to the **elements** of the international application:*

- ☒ the international application as originally filed
- ☒ the description:
 pages _____ 1 - 30 _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☒ the claims:
 pages _____ 1 - 42 _____, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the drawings:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☒ the sequence listing part of the description:
 pages _____ 19 - 28 _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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1. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

Claim 1, which the applicant filed on 26.07.2001 in reaction to the opinion of non-unity of invention established by the international Searching Authority is not considered to be an amendment pursuant to PCT Article 19, and is not taken into consideration in the present report.

However, for the examination of novelty and inventive step, the expression "in micro-organisms specific to the brewing process" was interpreted in the originally filed Claim 1, in the sense of the description as "in all micro-organisms specific to the brewing process".

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III

Pursuant to PCT Rule 66.1(e), claims relating to inventions for which no international search report has been established cannot be the subject matter of an international preliminary examination. This report therefore refers only to Claims 1 to 16, 18 to 20 (in part) and 26 (in full).

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: IV

The International Preliminary Examining Authority shares the opinion of the International Searching Authority that informed the applicant that Claims 1 to 41 as a whole contain fifteen different inventions that are not linked by a common inventive concept (PCT Rule 13.1). Since the applicant did not restrict the subject matter of the claims or pay additional search fees, the search is restricted to the first invention given, i.e. the subject matter of Claims 1 to 16, and 18 to 20 (all in part) and 26 (in full), that refer to the following subject matter:

nucleic acid molecule as a probe or primer according to SEQ ID NO:1,21,73,74, derivatives thereof and combinations thereof for determining lactobacillus brevis, and applications, methods and kits using these nucleic acid molecules.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1.	Statement			
	Novelty (N)	Claims	1-8, 11-13, 15, 16, 18 (all in part)	YES
		Claims	9, 10, 14, 19, 20 (all in part); 26 (in full)	NO
	Inventive step (IS)	Claims	1-8, 15, 16, 18 (all in part)	YES
		Claims	11-13 (all in part)	NO
	Industrial applicability (IA)	Claims	1-16, 18-20 (all in part); 26 (in full)	YES
		Claims		NO

2. Citations and explanations

The following international search report citations are considered to be the closest prior art:

D1 PATENT ABSTRACTS OF JAPAN vol. 017, no. 278 (C-1065), 28 May 1993 (1993-05-28) & JP-A-05 015400 (SAPPORO BREWERIES LTD), 26 January 1993 (1993-01-26)

D2 US-A-5 484 909 (NIETUPSKI RAYMOND M ET AL) 16 January 1996 (1996-01-16) cited in the application.

1. A method according to Claim 1, in which primers are used that "hybridise with a region of a microbial nucleic acids, which region is preserved in **all** micro-organisms specific to the brewing process" (for this expression see also Box VIII of the report) does not seem to be disclosed or suggested in the known prior art (PCT Article 33(2) and (3)). The same remark applies to dependent Claims 2 to 8 and 15, 16 and 18.

2. D1 discloses as sequence II a 20 nucleotide fragment of the sequence according to SEQ ID NO 1 of the present application (pos. 176-195). This disclosure is regarded as prejudicial to novelty for the

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subject matter of Claims 9, 10, 14, 19, 20 and 26
(PCT Article 33(2)).

Given the disclosure in D1 and D2 (Claims) the
subject matter of Claims 11 to 13 can be regarded as
non-inventive within the meaning of PCT Article
33(3).

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VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The expression "micro-organisms specific to the brewing process" (Claim 1) does not have a generally recognised meaning and is therefore unsuitable for describing certain micro-organisms, or distinguishing certain types from others. This expression is not clear and means that the claim does not satisfy the requirements of PCT Article 6.